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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/001,688
Filing Date: October 25, 2001
Appellant(s): SANA ET AL.

Theodore R. Sana
Paul K. Wolber
Clotilde S. Perbost
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed July 25, 2005 appealing from the Office action mailed February 24, 2005.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings, which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

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5,604,097 Brenner 2-1997

Oliva et al. "Fluorescence In Situ Hybridization Method for Co-Localization of mRNA and GFP" BioTechniques, Vol. 31(1), 2001, pg. 74-81.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2. Claims 6-8, 15-18 and 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brenner (5,604,097, issued February 18, 1997) in view of Oliva et al, (BioTechniques, 2001, Vol. 31(1) pg. 74-76 and 78-81).

Brenner discloses a method of tracking, identifying and sorting classes of molecules by the use of oligonucleotide tags. The tag is immobilized on the solid support, which comprises a wide variety of composition including glass (See column 12, lines 40-47). The solid support may comprise micro particles or arrays where uniform population of tag complements is synthesized (See column 13, lines 7-9 and column 35, lines 1-18). The oligonucleotide tag is covalently or non-covalently linked to the surfaces of the microparticle supports (See column 13, lines 52-58). The oligonucleotide tag is from 12 to 60 nucleotides in length (See column 9, line 14-15).

Brenner does not disclose that the hybridization is performed in the presence of urea with the concentration, 4M at about 50^0 C.

Oliva et al. disclose *in situ* hybridization with urea hybridization buffer (See pg. 74, Protocol 1). The incubation reaction is over night at 50^0 C (See pg. 74, Protocol 1). The urea concentration used is 1.0, 2.0 and 4.0 M. (See pg. 78, Table 1).

One of ordinary skill in the art would have been motivated to modify the method of Brenner by applying urea hybridization buffer in the method for specific hybridization. Oliva et al. indicate that the hybridization buffer containing urea decreases the annealing temperature and the specificity of the hybridization is retained (See pg. 79, column 2, second paragraph). Thus, it would have been prima facie obvious to apply the hybridization buffer containing urea of Oliva et al. to make specific hybridization on the array of Brenner.

(10) Response to Argument

A. Claim rejections – 35 USC 112 second paragraph

The rejection of claims 6-8 and 15-23 under 35 U.S.C. 112, second paragraph is withdrawn.

B. Claim 19 is allowable.

C. Claim rejections – 35 USC under 35 U.S.C. 103(a) as being unpatentable over Brenner (5,604,097, issued February 18, 1997) in view of Oliva et al, (BioTechniques, 2001, Vol. 31(1) pg. 74-76 and 78-81).

The appeal brief filed July 25, 2005 traverses this rejection. Appellant's arguments have been fully considered but are not persuasive for the reason that follows.

At page 11 the brief argues that Brenner and Oliva et al. constitute non-analogous art. However Brenner discloses a method of tracking, identifying and sorting classes or subpopulation of molecules by the use of oligonucleotide tags. The oligonucleotide tags are attached to polynucleotides in a sample. The complement of the tags is immobilized on solid support. The tracking, identifying or sorting is done by specifically hybridizing the tags to their complements on the solid support (See the Abstract and column 3, lines 32-40). It is clear that the method of Brenner involves a hybridization reaction. Nevertheless, Brenner does not disclose that the hybridization is performed in the presence of urea with the concentration, 4M at about 50^0 C. Oliva et al. disclose in situ hybridization in which urea hybridization buffer is used (See pg. 74, Protocol 1). The incubation reaction is overnight at 50^0 C (See pg. 74, Protocol 1). The urea concentration used is 1.0, 2.0 and 4.0 M. (See pg. 78, Table 1). The brief also traverse that the conditions for the two hybridization reactions are significantly different. However, the argument regarding hybridization condition does not relate to any limitations required in the claims. Moreover, Brenner et al. disclose that the hybridization condition is sufficiently stringent so that perfectly matched sequences form stable duplexes (See column 16, lines 13-15). One of ordinary skill in the art would understand the stringent condition for a hybridization reaction and

that the stringent condition would be varied based upon each specific hybridization reaction. Oliva et al. disclose a varied hybridization condition in that urea is used in a hybridization buffer and thus, a lowered annealing temperature was ensured while the specificity of hybridization was retained (See pg. 80, column 2, second paragraph). Based upon the analysis above, Brenner et al. and Oliva et al. are analogous art and the references are reasonably combined.

At page 12, the brief argues that Brenner discloses that altering base-specific stability of nucleic acid duplexes in a hybridization assay would be undesirable. However, Brenner did not specifically indicate that urea is an undesirable reagent that alters base-specific stability of nucleic acid duplexes in a hybridization assay.

At page 13, the brief argues that there is no motivation to combine the two references to arrive at the claimed invention. However, the motivation is that Oliva et al. disclose that the nucleic acid destabilizing reagent, urea lowers annealing temperature and retains the specificity of hybridization (See pg. 80, column 2, second paragraph).

At page 14, the brief discusses the unexpected benefits of the presently claimed methods and compositions and the advantage of using urea in a hybridization buffer, which is present in the publication of MWG Biotech AG. However, as indicated in the teachings of Oliva et al. as set forth above, the claimed invention does not provide an unexpected result of using urea in a hybridization buffer.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Joyce Tung J.T

October 12, 2005

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